

APPENDIX C

FUTURE NEEDS FOR BIOMEDICAL TRANSDUCERS

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INTRODUCTION

The past decade has witnessed a dramatic increase in the use of engineering techniques in medicine. The increased emphasis on the interaction of these two scientific disciplines has resulted from a recognition that modern medical problems are losing their identity with a single traditional discipline. It follows that the major accomplishments of the future will be achieved by the utilization of carefully managed diverse interdisciplinary efforts.

With the increasing requirements for engineering techniques in medicine, the transducer has become an important and critical link in the chain between patient and physician. Since in many cases a transducer is the limiting factor in a sophisticated instrumentation system, careful study is required to distinguish between what *should* be monitored in a biomedical environment and what *can* be monitored.

In the broadest definition, a transducer can be considered to be any energy conversion device; but for the purpose of this discussion, the words transducer and sensor will be considered synonymous. It is a mistake to think of a transducer as an isolated device coupled to a signal processor because in solving significant problems, the total system must be considered.

PRESENT BIOMEDICAL USES FOR TRANSDUCERS

Biomedical transducers are used in the research laboratory, in the analytical laboratory, and in the clinical environment (including monitoring). In the research laboratory, the detailed studies of both cellular and comparative physiology have increased the need for means of sensing physiological processes--particularly at the cellular level. In the analytical laboratory, many needs exist for the analysis of such things as body fluids and cancerous

tissue. In the clinical environment, transducers are used as a diagnostic tool as well as in patient monitoring. In the area of patient monitoring, there is an increasing use of intensive care units, coronary care units, and respiratory care units in which sensors are taking an increasingly important part in monitoring the patient's condition over a 24-hour period. As a diagnostic tool, sensors are being used to measure physiological functions that the physician cannot measure otherwise.

FUTURE REQUIREMENTS FOR BIOMEDICAL TRANSDUCERS

The need for biomedical transducers can be divided into three general areas: improvements in existing transducers, development of transducers which exploit new physical science phenomena, and development of transducers which utilize new physiological phenomena.

Improvement of Existing Transducers

The first area concerns improvements in existing transducers in such areas as size, sensitivity, reliability, cost, noise, stability, safety, frequency response, and signal-to-noise ratio. Although these changes are evolutionary, they will require the highest quality of engineering effort simply because the easy improvements have already been made. The following are examples of some of the transducers that need improvement:

- ° Pressure transducers are needed in both the cardiovascular and urinary systems. There is a definite need to improve the existing pressure transducers--particularly in size, sensitivity and stability. In addition, as for all transducers, a significant reduction in cost is needed because of the dramatic increase in health care costs.
- ° For the measurement of both urine and blood flows, a smaller and more sensitive catheter flowmeter is needed. The existing units which use the electromagnetic principle are too large and too insensitive for clinical needs.
- ° There is a need for a low cost fluoroscopic X-ray image intensifier which has an improved sensitivity to X-rays, a greater brightness, and a time lag small enough to allow real time viewing of such things as heart action.

- ° Endoradiosondes are small devices, swallowed by the patient, which transmit information to a nearby receiver. Although pH has been measured for several years, there is also a need for measuring such things as partial oxygen pressure and bleeding sites by the use of these devices. In addition, there is a definite need for improved stability of the existing endoradiosondes.
- ° A further example concerns taking biopsies of small samples of tissue in the bronchus for lung cancer detection. At the present time, no device exists which can tell the physician whether the forceps are about to sample not only the tissue of the bronchus but also a nearby blood vessel, a situation which can result in an embarrassing hemorrhage.

Development of Unexploited Physical Phenomena

The second major class of transducer improvement is the need for transducers which utilize unexploited physical science phenomena. Some of the phenomena which have been used include mechanical, optical, acoustical, chemical, resistive, inductive, capacitive, photoelectric, piezoelectric, and thermoelectric transducers. However, it is clear that many problems cannot be solved by evolutionary changes but will require the innovative uses of new physical science phenomena. Many examples can be given:

- ° Ultrasonics has been used in a variety of medical applications including detection of cancer of the breast, liver, kidney, and eye as well as in observing mitral valve motion and shifts of the midline of the brain. However, a definite need exists for a new device which can convert the ultrasonic energy into visual information, for conventional ultrasonic viewing as well as ultrasonic holography viewing.
- ° Another important area where a need exists for unexploited physical phenomena is in cardiac output measurement. The heart is basically a pump, and the blood output requires precise measurement. Although several methods have been tried, an innovative approach to this problem is needed.
- ° Another significant problem is in the detection of deep-seated cancer. Cancer at the present time has a good chance of cure if it is detected early enough, most cures being effected on superficial cancers such as skin, breast, and cervical. However, for deep-seated cancers such

as in the lung and stomach, the cancer has usually advanced too far for successful treatment by the time it is detected.

- ° Another difficult problem concerns the measurement of pleural pressure or the pressure in the pleural cavity surrounding the lungs. In a normal person, this cavity is generally not filled, but certain diseases cause the cavity to begin filling. There is a need for a noninvasive method of measuring this pleural pressure with precision.
- ° One of the most common measurements made in medicine today is blood pressure, yet significant improvements need to be made for patient monitoring. The conventional noninvasive method of measuring blood pressure requires that a cuff be inflated around the arm, but this occlusive cuff technique clearly is unsuitable for long-term monitoring of a critically ill patient. Although a number of ingenious approaches have been made in new methods of blood pressure detection, a desperate need still exists for a noninvasive blood pressure transducer which does not significantly disturb the patient.
- ° Another very common measurement in patient monitoring is chemical analysis of body fluids such as urine and blood. There is a need for an on-line device to measure constituents of the blood such as sugar, lactates, and pyruvates as well as a need for a device for rapid analytical urine measurement. For on-line measurements, significant breakthroughs will require new approaches such as the recent use of mass spectrometers.
- ° Another need for the use of unexploited physical science phenomena in transducer design is in the area of detecting atherosclerosis. This disease is one of the major causes of death in this country, and detection of the deposits which characterize the disease are a significant problem. New methods of detection are needed--particularly by noninvasive methods.

Development of Unutilized Physiological Phenomena

The third major class of transducer improvement is the need for utilization of new physiological phenomena--particularly in the area of patient monitoring. An overemphasis has been placed on monitoring temperature, pulse, respiration, and blood pressure instead of the useful information that the physician now obtains by personal observation. Proof of this overemphasis on

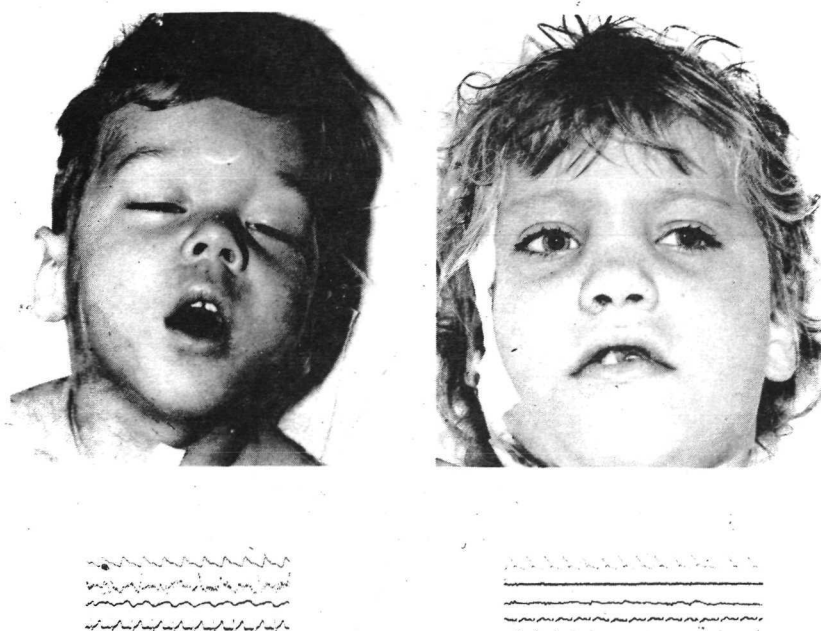


Figure 1. Two Patients Following Open-Heart Surgery (After Maloney).

monitoring can be seen in a simple example: Suppose a patient who had the usual transducers attached to him fell out of bed and was knocked unconscious. The variables that were being monitored would still fall within normal limits and a nurse at a central station would not detect the fact that her patient was lying on the floor unconscious. Although the purpose of monitoring is not merely to detect falling patients, this example does graphically illustrate the fact that monitoring the easy variables is clearly insufficient.

Dr. James V. Maloney, Chief of Thoracic Surgery at the UCLA School of Medicine, recently addressed this very point by saying, "As I approach the bedside as a clinician, despite my interest in computers, monitoring, and physical sciences in general, 95 percent of the useful information that I obtain in evaluating the patient comes from talking with him, seeing him, smelling him, and feeling him. One of the last things I ask for is a graphic chart that presents temperature, pulse, respiration, and blood pressure."¹ His observation demonstrates that the brain of the physician is able to integrate considerable information which existing transducers do not detect.

One key factor in this detection process is pattern recognition. For example, the pattern recognition capabilities of any physician would enable him to predict that of the two patients in Figure 1, the patient on the left was going to die, and the one on the right was going to survive--despite the

fact that the four channels of analogue data on both patients look quite normal. How do we recognize the nature of the patient's condition on the left despite the normal physiological data? Actually, we do not know, but at some future time when the cognitive processes are understood, it will be possible to design a meaningful monitoring system.

Many examples of this class of transducer could be given, but these three will illustrate:

- ° One example of the need for use of new physiological phenomena in monitoring concerns the ability of a trained physician to easily detect some things that a transducer cannot. Many physicians who have worked in a large city hospital have experienced the situation in which six or eight individuals were in the emergency room with gunshot or knife wounds--some minor and some serious. At a glance, a trained physician can tell those who are hypoxemic, those who are anemic, and those who are in shock. He can diagnose these conditions even though there is a dark melanin pigment in the skin of Negro patients. Obviously, the physician has learned something that enables him to quickly detect the patient's condition, but no transducers are available which can do this. It is not desirable to simply duplicate the physician's ability, but this example points out the fact that valuable physiological phenomena are not being utilized in detecting a patient's condition.
- ° Another example of this need is in the quest for cellular information. Medical research is probing deeper and deeper into the fundamental processes that occur in the human body. A common need in this quest is a method of measuring pressure within a single human cell. It is fairly certain that a new concept in transducing that utilizes a different physiological phenomenon is needed in order to detect this pressure.
- ° Another example which was mentioned earlier is the need for a means of detecting deep-seated cancers. This detection requirement is so significant that not only should unexploited physical science phenomena be used, but the utilization of some different physiological characteristics of the tumor will probably also be necessary. These